

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

MERCK & CO., INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 06-230 (GMS)
v.	)	
	)	<b>JURY TRIAL DEMANDED</b>
APOTEX, INC.	)	
	)	
Defendant.	)	

**APOTEX INC.'S MOTION FOR LEAVE TO SUBSTITUTE CORRECTED  
EXHIBITS TO ITS PENDING MOTION FOR LEAVE**

Defendant Apotex, Inc. ("Defendant" or "Apotex") moves for leave to substitute, in its pending Motion for Leave (D.I. 28), a Corrected First Amended Answer, Affirmative Defenses, and Counterclaims, attached hereto as Exhibits A and B (B is the black-lined version), for the First Amended Answer, Affirmative Defenses, and Counterclaims, attached as Exhibits A and B to its Motion for Leave (D.I. 28).

On October 13, 2006, Apotex filed a motion for leave to file its First Amended Answer, Affirmative Defenses, and Counterclaim. (D.I. 28) On November 1, 2006, Apotex learned that two numbered paragraphs in its First Amended Answer, Affirmative Defenses, and Counterclaims, specifically, paragraphs 39 and 42, contained allegations that were not correct. Therefore, Apotex moves to submit a corrected version of its First Amended Answer, Affirmative Defenses, and Counterclaims as an Exhibit to its Motion for Leave. The corrected version is identical to the former version except former paragraphs 39 and 42 have been deleted in their entirety and the remaining paragraphs have been renumbered. The attached corrected version would substitute the version previously attached as Exhibits A and B to its Motion for Leave.

The Court has not yet ruled on Apotex's Motion for Leave. Indeed, Plaintiff Merck & Co., Inc.'s ("Plaintiff's" or "Merck's") response to the Motion for Leave is due November 7, 2006. Merck will not be prejudiced by the filing of this corrected version. Following a meet and confer pursuant to Local Rule 7.1.1, counsel for Merck does not agree to this motion which is made solely for the purpose of substituting the corrected version for the former version in the previously filed Motion for Leave.

WHEREFORE, Apotex requests leave to substitute the Corrected First Amended Answer, Affirmative Defenses, and Counterclaims, attached hereto as Exhibits A and B, for the First Amended Answer, Affirmative Defenses, and Counterclaims, attached as Exhibits A and B to its Motion for Leave (D.I. 28).

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Dated: November 3, 2006

*Attorneys for Defendant Apotex, Inc.*

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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

**CERTIFICATE OF SERVICE**

I, Richard L. Horwitz, hereby certify that on November 3, 2006, the attached document was hand delivered on the following person and was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

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I hereby certify that on November 3, 2006, I have Electronically Mailed the attached document to the following:

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I hereby certify that on November 3, 2006, I have Federal Expressed the attached document to the following non-registered participants:

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# **EXHIBIT A**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

MERCK & CO., INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 06-230 (GMS)
v.	)	
	)	<b>JURY TRIAL DEMANDED</b>
APOTEX, INC.	)	
	)	
Defendant.	)	

**DEFENDANT APOTEX, INC.'S CORRECTED FIRST AMENDED  
ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendant, Apotex, Inc. ("Defendant" or "Apotex"), for its First Amended Answer, Affirmative Defenses, and Counterclaim, to the complaint of Merck & Co., Inc. ("Plaintiff" or "Merck"), states and alleges as follows:

**THE PARTIES**

1. Plaintiff Merck is a corporation incorporated under the laws of New Jersey with its principal place of business at One Merck drive, Whitehouse Station, New Jersey 08889.

**ANSWER:** Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore denies same.

2. On information and belief, Defendant Apotex, Inc. ("Apotex") is a Canadian company with offices at 150 Signet Drive, Toronto, Canada M9L 1T9. It has authorized Apotex Corp., incorporated under the laws of Delaware and with principal place of business at 2400 North Commerce Parkway, Suite 400 Weston, Florida 33326, to act as agent for service of process with respect to commencement of this patent infringement action.

**ANSWER:** Admitted.

**JURISDICTION AND VENUE**

3. This action arises under the patent laws of the United States of America and jurisdiction is founded on Title 28, United States Code §§ 1331 and 1338(a).

**ANSWER:** Apotex admits that Merck purports to bring an action under the patent laws of the United States of America and admits that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a); otherwise denied.

4. Venue is proper in this court under Title 28, United States Code §§ 1391(c) and 1400(b), because the defendant has submitted to personal jurisdiction in this judicial district for this action.

**ANSWER:** Admitted.

### **BACKGROUND**

5. On October 25, 1994, United States Letters Patent No. 5,358,941 (the “‘941 patent”), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS WITH LACTOSE, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The ‘941 patent is currently set to expire on December 2, 2012. The ‘941 patent discloses and claims novel pharmaceutical compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget’s disease, malignant hypercalcemia, and metastatic bone disease. A copy of the ‘941 patent is attached to this Complaint as Exhibit 1.

**ANSWER:** Apotex admits that United States Patent No. 5,358,941, entitled “Dry Mix Formulation For Bisphosphonic Acids With Lactose” was issued by the United States Patent and Trademark Office on October 25, 1994 to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare, and that a copy of the ‘941 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

6. On October 28, 1997, United States Letters Patent No. 5,681,590 (the “‘590 patent”), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The ‘590 patent is currently set to expire on December 2, 2012. The ‘590 patent discloses and claims novel pharmaceutical compositions and novel processes for manufacturing compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget’s disease, malignant

hypercalcemia, and metastatic bone disease. A copy of the '590 patent is attached to this Complaint as Exhibit 2.

**ANSWER:** Apotex admits that United States Patent No. 5,681,590, entitled "Dry Mix Formulation For Bisphosphonic Acids" was issued by the United States Patent and Trademark Office on October 28, 1997 to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare, and that a copy of the '590 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

7. On December 15, 1998, United States Letters Patent No. 5,849,726 (the "'726 patent"), entitled ANHYDROUS ALENDRONATE MONOSIDUM SALT FORMULATIONS, duly and legally issued to Gerald S. Brenner, Drazen Ostovic, Earl R. Oberholtzer, Jr., and J. Eric Thies. The '726 patent is currently set to expire on June 6, 2015. The '726 patent discloses and claims novel pharmaceutical compositions of anhydrous 4-amino-1-hydroxy-butyldiene-1, 1-bisphosphonic acid monosodium salt, as well as novel methods for treating and preventing bone loss with these compositions. A copy of the '726 patent is attached to this Complaint as Exhibit 3.

**ANSWER:** Apotex admits that United States Patent No. 5,849,726, entitled "Anhydrous Alendronate Monosidum Salt Formulations" was issued by the United States Patent and Trademark Office on December 15, 1998 to Gerald S. Brenner, Drazen Ostovic, Earl R. Oberholtzer, Jr., and J. Eric Thies, and that a copy of the '726 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

8. On December 28, 1999, United States Letters Patent No. 6,008,207 (the "'207 patent"), entitled ANHYDROUS ALENDRONATE MONOSIDUM SALT FORMULATIONS, duly and legally issued to Gerald S. Brenner, Drazen Ostovic, Earl R. Oberholtzer, Jr., and J. Eric Thies. The '207 patent is currently set to expire on June 6, 2015. The '207 patent discloses and claims novel methods for administering anhydrous



alendronate monosodium salt formulations. A copy of the '207 patent is attached to this Complaint as Exhibit 4.

**ANSWER:** Apotex admits that United States Patent No. 6,008,207, entitled "Anhydrous Alendronate Monosodium Salt Formulations" was issued by the United States Patent and Trademark Office on December 28, 1999 to Gerald S. Brenner, Drazen Ostovic, Earl R. Oberholtzer, Jr., and J. Eric Thies, and that a copy of the '207 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

9. On July 18, 2000, United States Letters Patent No. 6,090,410 (the "'410 patent"), entitled ANHYDROUS ALENDRONATE MONOSIDIUM SALT FORMULATIONS, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The '410 patent is currently set to expire on December 2, 2012. The '410 patent discloses and claims novel pharmaceutical compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget's disease, malignant hypercalcemia, and metastatic bone disease. A copy of the '410 patent is attached to this Complaint as Exhibit 5.

**ANSWER:** Apotex admits that United States Patent No. 6,090,410, entitled "Anhydrous Alendronate Monosodium Salt Formulations" was issued by the United States Patent and Trademark Office on July 18, 2000 to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare, and that a copy of the '410 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

10. On February 27, 2001, United States Letters Patent No. 6,194,004 (the "'004 patent"), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The '004 patent is currently set to expire on December 2, 2012. The '004 patent discloses and claims novel pharmaceutical compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis,

Paget's disease, malignant hypercalcemia, and metastatic bone disease. A copy of the '004 patent is attached to this Complaint as Exhibit 6.

**ANSWER:** Apotex admits that United States Patent No. 6,194,004, entitled "Dry Mix Formulation For Bisphosphonic Acids" was issued by the United States Patent and Trademark Office on February 27, 2001 to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare, and that a copy of the '004 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

11. On November 30, 1999, United States Letters Patent No. 5,994,329 (the "'329 patent") duly and legally issued to Anastasia G. Daifotis, Arthur C. Santora, II, and John Yates entitled METHOD FOR INHIBITING BONE RESORPTION. The '329 patent is currently set to expire on July 17, 2018. The '329 patent discloses and claims methods for inhibiting bone resorption in mammals while minimizing the occurrence of or potential for adverse gastrointestinal effects, and pharmaceutical compositions and kits for carrying out these therapeutic methods. A copy of the '329 patent is attached to this Complaint as Exhibit 7.

**ANSWER:** Apotex admits that United States Patent No. 5,994,329, entitled "Method For Inhibiting Bone Resorption" was issued by the United States Patent and Trademark Office on November 30, 1999 to Anastasia G. Daifotis, Arthur C. Santora, II, and John Yates, and that a copy of the '329 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

12. On January 18, 2000, United States Letters Patent No. 6,015,801 (the "'801 patent") duly and legally issued to Anastasia G. Daifotis, A. John Yates, and Arthur C. Santora, II entitled METHOD OF INHIBITING BONE RESORPTION. The '801 patent is currently set to expire on July 17, 2018. The '801 patent discloses and claims methods for inhibiting bone resorption in mammals while minimizing the occurrence of or potential for adverse gastrointestinal effects, and pharmaceutical

compositions and kits for carrying out these therapeutic methods. A copy of the '801 patent is attached to this Complaint as Exhibit 8.

**ANSWER:** Apotex admits that United States Patent No. 6,015,801, entitled "Method Of Inhibiting Bone Resorption" was issued by the United States Patent and Trademark Office on January 18, 2000 to Anastasia G. Daifotis, A. John Yates, and Arthur C. Santora, II, and that a copy of the '801 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

13. On May 1, 2001, United States Letters Patent No. 6,225,294 (the "'294 patent") duly and legally issued to Anastasia G. Daifotis, Arthur C. Santora, II and John Yates entitled METHOD OF INHIBITING BONE RESORPTION. The '294 patent is currently set to expire July 17, 2018. The '294 patent discloses and claims methods for inhibiting bone resorption in mammals while minimizing the occurrence of or potential for adverse gastrointestinal effects, and pharmaceutical compositions and kits for carrying out these therapeutic methods. A copy of the '294 patent is attached to this Complaint as Exhibit 9.

**ANSWER:** Apotex admits that United States Patent No. 6,225,294, entitled "Method Of Inhibiting Bone Resorption" was issued by the United States Patent and Trademark Office on May 1, 2001 to Anastasia G. Daifotis, Arthur C. Santora, II, and John Yates, and that a copy of the '294 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

14. Merck is the owner through assignment of the '941, '590, '726, '207, '410, '004, '329, '801 and '294 patents. Merck also owns an approved New Drug Application (NDA No. 20-560) for alendronate sodium tablets that are sold under its trademark FOSAMAX®.

**ANSWER:** Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore denies same.

15. The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (“FDA”) under the Federal Food, Drug, and Cosmetic Act. Merck listed the ‘941, ‘590, ‘726, ‘207, ‘410, ‘004, ‘329, ‘801, and ‘294 patents in the Orange Book for its FOSAMAX<sup>®</sup> tablets.

**ANSWER:** Apotex admits that the ‘941, ‘590, ‘726, ‘207, ‘410, ‘004, ‘329, ‘801, and ‘294 patents are listed in the “Orange Book” for Fosamax<sup>®</sup> tablets and denies the truth of the remaining averments in this paragraph.

16. The FDA granted a six-month period of market exclusivity beyond the patent terms for Merck’s FOSAMAX<sup>®</sup> drug product due to the timely submission and acceptance of pediatric studies pursuant to 21 U.S.C. § 355a(c). This six-month period is also listed in the Orange Book. The FDA may therefore not approve to market generic versions of Merck’s FOSAMAX<sup>®</sup> tablets until six months after the expiration date of the ‘941, ‘590, ‘726, ‘207, ‘410, ‘004, ‘329, ‘801, and ‘294 patents. The six-month “pediatric exclusivity period” expires on June 2, 2013, for the ‘941 patent; June 2, 2013, for the ‘590 patent; December 6, 2015, for the ‘726 patent; December 6, 2015, for the ‘207 patent; June 2, 2013, for the ‘410 patent; June 2, 2013, for the ‘004 patent; January 17, 2019, for the ‘329 patent; January 17, 2019, for the ‘801 patent; and January 17, 2019, for the ‘294 patent. The FDA also may not approve to market generic versions of Merck’s FOSAMAX<sup>®</sup> tablets until the expiration of all other patents and the subsequent pediatric exclusivity period listed in the Orange Book.

**ANSWER:** Apotex admits that the Orange Book shows the pediatric exclusivity period for the patents as stated in the averments in this paragraph and Apotex denies the remaining averments in this paragraph.

17. On information and belief, an Abbreviated New Drug Application (ANDA No. 077-982) has been filed on behalf of Apotex, including a certification under Title 21, United States Code § 355(j)(2) with the FDA for 5 mg, 10 mg, 35 mg, and 70 mg alendronate sodium tablets. Apotex’s ANDA No. 077-982 allegedly contains a certification of invalidity, unenforceability, and/or noninfringement of the ‘941, ‘590, ‘726, ‘207, ‘410, ‘004, ‘329, ‘801, and ‘294 patents. Notice of that certification, but not the certification, was transmitted to Merck on or after February 24, 2006.

**ANSWER:** Admitted.

18. On information and belief, Apotex filed ANDA No. 077-982 because it seeks to enter the market that FOSAMAX<sup>®</sup> pharmaceutical products have created due to their benefits and advantages.

**ANSWER:** Denied, except to admit that Apotex seeks permission from the FDA to sell a generic version of Fosamax<sup>®</sup>.

**COUNT I**

19. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

**ANSWER:** Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

20. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '941 patent, before the expiration of the '941 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

21. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '941 patent, it was aware of the existence of the '941 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

**ANSWER:** Apotex admits it was aware of the '941 patent at the time it filed ANDA No. 077-982; otherwise denied.

22. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '941 patent.

**ANSWER:** Denied.

23. On information and belief, the infringement by Apotex of the '941 patent was and is willful.

**ANSWER:** Denied.

24. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

**ANSWER:** Denied.

**COUNT II**

25. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

**ANSWER:** Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

26. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '590 patent, before the expiration of the '590 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

27. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '590 patent, it was aware of the existence of the '590 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

**ANSWER:** Apotex admits it was aware of the '590 patent at the time it filed ANDA No. 077-982; otherwise denied.

28. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '590 patent.

**ANSWER:** Denied.

29. On information and belief, the infringement by Apotex of the '590 patent was and is willful.

**ANSWER:** Denied.

30. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

**ANSWER:** Denied.

**COUNT III**

31. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

**ANSWER:** Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

32. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '726 patent, before the expiration of the '726 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

33. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '726 patent, it was aware of the existence of the '726 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

**ANSWER:** Apotex admits it was aware of the '726 patent at the time it filed ANDA No. 077-982; otherwise denied.

34. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '726 patent.

**ANSWER:** Denied.

35. On information and belief, the infringement by Apotex of the '726 patent was and is willful.

**ANSWER:** Denied.

36. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

**ANSWER:** Denied.

**COUNT IV**

37. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

**ANSWER:** Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

38. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '207 patent, before the expiration of the '207 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

39. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '207 patent, it was aware of the existence of the '207 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

**ANSWER:** Apotex admits it was aware of the '207 patent at the time it filed ANDA No. 077-982; otherwise denied.

40. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '207 patent.

**ANSWER:** Denied.

41. On information and belief, the infringement by Apotex of the '207 patent was and is willful.

**ANSWER:** Denied.

42. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

**ANSWER:** Denied.

#### **COUNT V**

43. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.



**ANSWER:** Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

44. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '410 patent, before the expiration of the '410 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

45. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '410 patent, it was aware of the existence of the '410 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

**ANSWER:** Apotex admits it was aware of the '410 patent at the time it filed ANDA No. 077-982; otherwise denied.

46. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '410 patent.

**ANSWER:** Denied.

47. On information and belief, the infringement by Apotex of the '410 patent was and is willful.

**ANSWER:** Denied.

48. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

**ANSWER:** Denied.

#### **COUNT VI**

49. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

**ANSWER:** Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

50. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '004 patent, before the expiration of the '004 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

51. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '004 patent, it was aware of the existence of the '004 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

**ANSWER:** Apotex admits it was aware of the '004 patent at the time it filed ANDA No. 077-982; otherwise denied.

52. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '004 patent.

**ANSWER:** Denied.

53. On information and belief, the infringement by Apotex of the '004 patent was and is willful.

**ANSWER:** Denied.

54. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

**ANSWER:** Denied.

## **COUNT VII**

55. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

**ANSWER:** Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

56. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '329 patent,

before the expiration of the '329 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

57. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '329 patent, it was aware of the existence of the '329 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

**ANSWER:** Apotex admits it was aware of the '329 patent at the time it filed ANDA No. 077-982; otherwise denied.

58. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '329 patent.

**ANSWER:** Denied.

59. On information and belief, the infringement by Apotex of the '329 patent was and is willful.

**ANSWER:** Denied.

60. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

**ANSWER:** Denied.

### **COUNT VIII**

61. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

**ANSWER:** Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

62. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use or sale of a drug product the use of which is claimed in the '801 patent, before the expiration of the '801 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

63. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '801 patent, it was aware of the existence of the '801 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

**ANSWER:** Apotex admits it was aware of the '801 patent at the time it filed ANDA No. 077-982; otherwise denied.

64. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '801 patent.

**ANSWER:** Denied.

65. On information and belief, the infringement by Apotex of the '801 patent was and is willful.

**ANSWER:** Denied.

66. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

**ANSWER:** Denied.

### **COUNT IX**

67. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

**ANSWER:** Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

68. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '294 patent, before the expiration of the '294 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

69. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '294 patent, it was aware of the existence of the '294 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

**ANSWER:** Apotex admits it was aware of the '294 patent at the time it filed ANDA No. 077-982; otherwise denied.

70. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '294 patent.

**ANSWER:** Denied.

71. On information and belief, the infringement by Apotex of the '294 patent was and is willful.

**ANSWER:** Denied.

72. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

**ANSWER:** Denied.

WHEREFORE, Defendant prays that Plaintiff take nothing from this action and its complaint be dismissed with prejudice, with costs assessed against Plaintiff.

### **AFFIRMATIVE DEFENSES**

#### **First Affirmative Defense**

The complaint and each Count thereof fails to state a claim upon which relief can be granted.

#### **Second Affirmative Defense**

After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents are invalid and/or unenforceable for failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

#### **Third Affirmative Defense**

Merck is collaterally estopped from asserting the validity of the '329 patent against Apotex by virtue of the final decision of the United States Court of Appeals for the Federal Circuit in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed.Cir. 2005), *reh'g and reh'g en banc denied*, 405 F.3d 1388, *cert. denied*, 126 S.Ct. 488 (2005), which invalidated the relevant claims of that patent{ TA \l "*Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed.Cir. 2005), *reh'g and reh'g en banc denied*, 405 F.3d 1388, *cert. denied*, 126 S.Ct. 488 (2005)" \s "*Merck v. Teva*, 395 F.3d 1364" \c 1 }.

#### **Fourth Affirmative Defense**

Merck is collaterally estopped from asserting the validity of the '801 patent against Apotex by virtue of the final decision of the United States Court of Appeals for the Federal Circuit in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed.Cir. 2005), *reh'g and reh'g en banc denied*, 405 F.3d 1388, *cert. denied*, 126 S.Ct. 488 (2005), which prevents Merck from asserting the validity of the relevant claims of that patent.

#### **Fifth Affirmative Defense**

Merck is collaterally estopped from asserting the validity of the '294 patent against Apotex by virtue of the final decision of the United States Court of Appeals for the Federal Circuit in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed.Cir. 2005), *reh'g and reh'g en banc denied*, 405 F.3d 1388, *cert. denied*, 126 S.Ct. 488 (2005), which prevents Merck from asserting the validity of the relevant claims of that patent.

## **COUNTERCLAIM**

Counterclaimant Apotex, Inc. (“Apotex”) for its counterclaim against counter-defendant Merck & Co., Inc. (“Merck”) alleges as follows:

### **NATURE OF THE ACTION**

1. Apotex’s claims arise out of Merck’s anti-competitive scheme of filing infringement suits it knows, or should know, are baseless and then presenting the alleged infringer with a covenant not to sue in order to avoid an adverse decision on the merits with the intent of preventing or delaying Apotex and other secondary generic applicants from marketing a generic version of alendronate sodium that would compete with Merck’s highly lucrative brand version called Fosamax®, used in the treatment and prevention of osteoporosis and Paget’s disease.

### **PARTIES AND JURISDICTION**

2. Apotex is a Canadian company with offices at 150 Signet Drive, Toronto, Canada M9L 1T9.

3. On information and belief, Merck is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

4. This Counterclaim arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355) (hereinafter “Hatch-Waxman Amendments”), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066{ TA \l "117 Stat. 2066 (2003)" \s "117 Stat. 2066" \c 2 } (2003) (hereinafter “MMA”); the

Antitrust Laws of the United States, particularly the Sherman Antitrust Act, 15 U.S.C. § 2; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. This Court has subject matter jurisdiction over this Counterclaim pursuant to 28 U.S.C. §§ 1331, 1332, 1337, 1338(a), and 2201.

6. Venue and personal jurisdiction are proper in this district because Merck, *inter alia*, is subject to personal jurisdiction in this judicial district and has submitted itself to the jurisdiction of this Court.

### **HATCH-WAXMAN SCHEME**

7. The Hatch-Waxman Amendments established a simplified procedure for FDA approval of generic drugs in order to make low cost generic drugs more available.

8. The FDA must approve all drugs before they can be introduced in interstate commerce.

9. Under the Hatch-Waxman Amendments, a manufacturer that seeks to market a generic drug may submit an Abbreviated New Drug Application (“ANDA”) for approval by the FDA, rather than submitting a New Drug Application (“NDA”) concerning the safety and efficacy of the generic drug, and it may rely on safety and efficacy studies previously submitted by the pioneer manufacturer by submitting information showing the generic drug’s bioequivalence with the previously approved drug product.

10. Also under the Hatch-Waxman Amendments, a pioneer drug manufacturer that holds an approved NDA is required to notify the FDA of all patents that claim the drug for which the NDA applicant submitted the application. The FDA lists such patents



related to a specific drug in its “Approved Drug Products With Therapeutic Equivalence Evaluations” (otherwise known as the “Orange Book”).

11. As part of the approval process, an ANDA applicant must make a certification addressing each patent listed in the Orange Book that claims the drug.

12. More specifically, the applicant must certify that (I) no such patent information has been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is submitted. These are commonly referred to as paragraph I, II, III, and IV certifications.

13. When an ANDA contains a paragraph IV certification, the generic manufacturer must give notice to the patentee and the NDA holder and provide a detailed basis for its belief that the patent is not infringed, invalid, or unenforceable.

14. Under the Hatch-Waxman Amendments, making a paragraph IV certification is an act of infringement.

15. Upon receipt of a paragraph IV certification, the patentee then has forty-five days to sue the generic manufacturer for patent infringement.

16. If the patentee does not file an infringement suit within forty-five days of receiving a paragraph IV notification, the FDA may approve the ANDA once all FDA exclusivities have expired and the FDA determines that the proposed generic is bioequivalent to the approved drug and is otherwise approvable.

17. If the patentee does file an infringement action, FDA approval is automatically stayed for thirty months, or until the court hearing the infringement case

determines that the patent(s) is invalid, not infringed, or unenforceable, or the patent(s) expires, whichever is earlier.

18. The first ANDA holder (first generic filer) to file a paragraph IV certification is entitled to a 180-day period of exclusivity, during which time the FDA will not approve any other ANDAs containing paragraph IV certifications that list the same pioneer drug.

19. The 180-day exclusivity period does not begin to run until the first generic filer markets the drug or there is a decision by the court (in a suit against any generic manufacturer who makes a paragraph IV certification for the drug at issue) finding that the patent(s) listed in the Orange Book are either invalid or not infringed, whichever is earlier.

**MERCK'S PATENTS RELATING TO FOSAMAX®**

20. Merck is the owner of a number of patents listed in the Orange Book for the drug alendronate sodium, which is sold by Merck under the trademark Fosamax®.

21. Launched in 1995, Fosamax® is used for the treatment and prevention of osteoporosis and for the treatment of Paget's disease.

22. Fosamax® was Merck's second largest selling drug in 2005, with nearly \$3.2 billion in sales worldwide.

23. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Fosamax® is a vitally important component in Merck's drug portfolio and Merck is interested in maintaining its market share and profits for as long as it can.

24. Currently, Merck's market share is protected by its patents covering Fosamax® that are listed in the Orange Book.

25. The active ingredient in Fosamax® is alendronate sodium. Merck's patent on this active ingredient is U.S. Pat. No. 4,621,077 ("the '077 patent").

26. The '077 patent is set to expire on August 6, 2007, but Merck has an additional FDA exclusivity until February 6, 2008.

27. The '077 patent was found valid in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 228 F.Supp.2d 480 (D.Del. 2002), *aff'd*, 347 F.3d 1367 (Fed.Cir. 2003){ TA \l "*Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 228 F.Supp.2d 480 (D.Del. 2002), *aff'd*, 347 F.3d 1367 (Fed.Cir. 2003)" \s "*Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 228 F.Supp.2d 480 (D.Del. 2002), *aff'd*, 347 F.3d 1367 (Fed.Cir. 2003)" \c 1 }.

28. Merck also has a number of other patents that it is using to extend its monopoly of alendronate sodium. These patents relate, however, to various formulations of the active ingredient and to dosage strategies.

29. The patents directed to the alendronate sodium formulations that Merck asserted in its complaint are: U.S. Patent Nos. 5,358,941 ("the '941 patent"), 5,681,590 ("the '590' patent"), 5,894,726 ("the '726 patent"), 6,008,207 ("the '207 patent"), 6,090,410 ("the '410 patent") and 6,194,004 ("the '004 patent"). The patents directed to the dosage regimens asserted in the complaint are: U.S. Patent Nos. 5,994,329 ("the '329 patent"), 6,015,801 ("the '801 patent"), and 6,225,294 ("the '294 patent").

30. The '941, '590, '410, and '004 patents are currently set to expire on December 2, 2012; the '726 and '207 patents are currently set to expire on June 6, 2015;

and the '329, '801, and '294 patents are currently set to expire on July 7, 2018. Each of these patents has an additional six months of FDA exclusivity beyond the patent expiration dates though.

**MERCK'S PRE-SUIT KNOWLEDGE**

31. Apotex filed an ANDA seeking approval for a generic version of alendronate sodium.

32. On February 24, 2006, Apotex provided its paragraph IV certification to Merck, notifying Merck that it had filed an ANDA for alendronate sodium and that, other than the '077 patent, the patents listed by Merck in the Orange Book for alendronate sodium, *i.e.*, the nine patents that are at issue in this case, were either invalid, unenforceable, and/or not infringed.

33. Specifically, Apotex told Merck that the '329 and '801 patents were invalid based upon a prior court decision which held that two claims of the '329 patent were invalid.

34. Apotex also told Merck that its ANDA did not infringe Merck's '941 patent at least because the claims of that patent are limited to a composition comprising anhydrous lactose, among other things, and Apotex's alendronate sodium tablets will not contain lactose (either anhydrous or hydrous).

35. Apotex further told Merck that the '590, '410, and '004 patents were not infringed by its ANDA because the claims of those patents were limited to a tablet containing either anhydrous lactose or hydrous fast flow lactose, and Apotex's tablets would not contain anhydrous lactose or hydrous fast flow lactose.

36. Apotex also told Merck that its ANDA would not infringe the '726, '207, and '294 patents because the claims of those patents were limited to anhydrous alendronate sodium, whereas, Apotex's tablets would not contain anhydrous alendronate sodium.<sup>1</sup>

37. Apotex made a paragraph III certification in its ANDA with respect to the '077 patent certifying that it would not market its generic version until the expiration of the '077 patent and its pediatric exclusivity, which were set to expire on February 6, 2008.

38. As required under the Hatch-Waxman scheme, Apotex offered in its paragraph IV certification to provide Merck with certain confidential information in order for Merck to determine whether Apotex's ANDA did in fact infringe Merck's patents, notwithstanding Apotex's paragraph IV certification, prior to Merck's filing an infringement lawsuit.

39. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that, prior to filing its infringement suit against Apotex, Merck knew it was within the ability of one of ordinary skill in formulating and manufacturing medications to make generic alendronate sodium tablets without using lactose (hydrous, anhydrous, or fast-flowing).

40. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that, prior to filing its infringement suit against Apotex, Merck knew it was within the ability of one of ordinary skill in formulating and

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<sup>1</sup> The '294 patent was mistakenly included with this set of patents when it should have been included with the '329 and '801 dosage patents. This mistake, however, should have been obvious to Merck because the '294 patent is a continuation of the application which became the '329 patent.

manufacturing medications to make generic alendronate sodium tablets by using hydrous alendronate sodium instead of anhydrous alendronate sodium.

41. On January 28, 2005, the Federal Circuit reversed the lower court and held that claims 23 and 37 of Merck's '329 patent relating to the once-weekly dosage of alendronate sodium were invalid as obvious. *See Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed.Cir. 2005), *reh'g and reh'g en banc denied*, 405 F.3d 1388, *cert. denied*, 126 S.Ct. 488 (2005){ TA \l "*Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed.Cir. 2005), *reh'g and reh'g en banc denied*, 405 F.3d 1388, *cert. denied*, 126 S.Ct. 488 (2005)" \s "Merck v. Teva, 395 F.3d 1364" \c 1 }. The Supreme Court denied Merck's petition for certiorari on October 17, 2005.

42. The '801 patent is related to the '329 patent in that it is a continuation-in-part of the same application of which the '329 is a continuation.

43. The '294 patent is related to the '329 patent in that it is a continuation of the application which became the '329 patent.

44. Merck knew prior to filing its infringement suit against Apotex, which asserts the '329 patent as well as the related dosage patents (the '801 and '294 patents), that its claims relating to the once-weekly dosage of alendronate sodium had been held invalid in a final, nonappealable decision.

45. Merck knew prior to filing its infringement suit against Apotex that the claims in the '329 patent related to alendronate sodium were invalid and unenforceable.

46. Merck knew prior to filing its infringement suit against Apotex that Merck had no objectively reasonable basis for believing that Apotex was infringing any valid claims of the patents that were the subject of Apotex's paragraph IV certification.

**MERCK'S SUING OF APOTEX**

47. Despite the foregoing, on April 7, 2006, Merck filed this patent infringement suit against Apotex.

48. Merck's filing of this lawsuit against Apotex imposed a 30 month stay, measured from Merck's receipt of Apotex's paragraph IV certifications, on the FDA's approval of Apotex's ANDA for alendronate sodium.

49. The 30 month stay will not expire until at least August 24, 2008, unless there is a court decision finding that the patents asserted in Apotex's paragraph IV certification are invalid or not infringed.

50. A dismissal of this case for lack of subject matter jurisdiction will not terminate the 30 month stay.

51. Thus, the filing of this lawsuit created a barrier to Apotex's entry into the market for generic alendronate sodium tablets.

52. The filing of this lawsuit was objectively baseless because Merck knew that the claims in the patents it was asserting were invalid and/or not infringed by Apotex's proposed alendronate sodium product as set forth in its ANDA.

53. The filing of this lawsuit was an objectively unreasonable effort by Merck to reduce competition in the market for generic alendronate sodium tablets.

54. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Merck brought this lawsuit in bad faith, knowing that the

patents it was asserting were invalid and/or not infringed by Apotex's alendronate sodium product as set forth in Apotex's ANDA, but intending to present a covenant not to sue so that it could avoid a court decision on the merits, thus maintaining the 30 month stay on Apotex's ANDA for alendronate sodium and avoiding a trigger of the 180 day exclusivity, all to keep Apotex out of the market longer than would be the case otherwise in order to maintain Merck's monopoly.

**MERCK'S UNILATERAL COVENANT NOT TO SUE**

55. After Merck filed its complaint against Apotex, Apotex subsequently provided Merck with certain confidential information from its ANDA in order to resolve this matter.

56. That information showed that Apotex does not use a formulation that is covered by Merck's formulation patents.

57. After Apotex provided its confidential information to Merck, Merck indicated that it would present Apotex with a covenant not to sue.

58. Merck refused to agree to any dismissal order in which the Court made any findings that Apotex did not infringe Merck's patents.

59. A decision by the court finding that all of Merck's listed patents are not infringed or invalid would terminate the automatic 30-month stay for FDA approval of Apotex's ANDA.

60. A court decision finding that all of Merck's listed patents are not infringed or invalid would also trigger the 180-day exclusivity period that is normally available to the first generic to file an ANDA, whether it has marketed the product or not.



61. On August 7, 2006, Merck unilaterally served on Apotex a covenant not to sue Apotex for infringement of any of the nine patents in suit based upon the importation, manufacture, use, sale, or offer for sale of the alendronate sodium tablets that are the subject of Apotex's ANDA for alendronate sodium.

62. Merck's unilaterally tendered covenant not to sue admits on its face that claims 23 and 37 of the '329 patent have been held invalid; and therefore could not be infringed.

63. Merck's unilaterally tendered covenant not to sue also admits on its face that based upon confidential information provided by Apotex the products that are the subject of Apotex's ANDA for alendronate sodium (1) will not contain anhydrous lactose or hydrous fast flow lactose, and (2) will not contain anhydrous alendronate sodium.

64. Merck's covenant not to sue Apotex for infringement of the nine patents in suit offers no protection to Apotex's potential customers against an infringement suit.

65. After serving Apotex with its covenant not to sue, Merck sought to dismiss its claims and Apotex's counterclaim for lack of subject matter jurisdiction.

66. A dismissal of this case based upon Merck's covenant not to sue will not terminate the 30 month stay, nor will it constitute a "court decision" triggering event for the 180 day exclusivity period.

67. Merck's covenant not to sue is a sham because Merck does not believe that Apotex's ANDA for alendronate sodium infringes any valid claims of Merck's patents in suit.

68. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support for the proposition that Merck's unjustified institution of this

lawsuit was done with the intention of establishing a 30 month stay on Apotex's generic drug application for alendronate sodium with foreknowledge that Merck would tender a covenant not to sue to deprive this Court of jurisdiction, yet maintain the 30 month stay.

69. A reasonable opportunity for further investigation or discovery is likely to provide evidence that shows that Merck unilaterally tendered its covenant not to sue with the intention of maintaining the 30 month stay on Apotex's generic drug application for alendronate sodium, and avoiding the "court decision" triggering event for the 180 day exclusivity period of the first generic filer for alendronate sodium.

70. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support to show that Merck tendered its covenant not to sue knowing that Apotex did not infringe any valid claim of the patents in suit.

71. A reasonable opportunity for further investigation and discovery is likely to provide evidentiary support that Merck tendered its covenant not to sue Apotex because it knew that its patents were invalid or not infringed by Apotex, and that the covenant tendered is a sham created to fend off the inevitable judgment of invalidity and non-infringement.

72. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support for the proposition that absent Merck's use of a sham covenant not to sue, Apotex would have obtained a "court decision" finding the patents invalid or not infringed, which would have terminated the 30 month stay and triggered the first generic applicant's 180 day exclusivity period thereby allowing Apotex to enter the market for generic alendronate sodium drug product as a therapeutic equivalent to Fosamax® market in February 2008.

73. A “court decision” finding the patents invalid and/or not infringed would also protect Apotex’s potential customers for alendronate sodium tablets.

**MERCK’S SUIT AGAINST WATSON LABORATORIES**

74. On September 7, 2005, Merck filed an infringement action in this district against Watson Laboratories, Inc. (“Watson”) (Case No. 05-cv-00658 (GMS)), in which Merck alleged that Watson’s ANDA for alendronate sodium infringed the same patents at issue in this case.

75. On October 19, 2005, Watson filed an answer and counterclaim. In its counterclaim, Watson sought a declaratory judgment that the patents asserted against it were either invalid or not infringed.

76. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support for the proposition that Merck subsequently presented Watson with an unsolicited covenant not to sue and then sought to dismiss the case and Watson’s counterclaim for lack of subject matter jurisdiction.

77. Over Watson’s objection, this Court subsequently dismissed Merck’s infringement claim and Watson’s counterclaim.

78. Merck was thus able to avoid a court decision triggering event in the Watson case, and as it stands now Watson is prevented from entering the market for generic alendronate sodium until 180 days after the first generic filer enters the market.

**MERCK’S ACTIONS AGAINST TEVA PHARMACEUTICALS USA INC.**

79. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support for the proposition that Teva Pharmaceuticals USA Inc. (“Teva”) holds the position of the first to file an ANDA for alendronate sodium.

80. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support for the proposition that Teva may enter the market for generic alendronate sodium when Merck's exclusivity expires on February 6, 2008.

81. On May 10, 2006, Merck sued Teva for relief from the judgment entered by mandate of the United States Court of Appeals for the Federal Circuit in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, (No. 04-1005) as a result of Teva's fraud, misrepresentations, or other misconduct. That appellate judgment was a reversal of the judgment entered in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, (C.A. No. 01-048 (JJF) (D.Del.)). The Federal Circuit held that claims 23 and 37 of Merck's '329 patent relating to the once-weekly dosage of alendronate sodium were invalid as obvious. *See Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed.Cir. 2005), *reh'g and reh'g en banc denied*, 405 F.3d 1388, *cert. denied*, 126 S.Ct. 488 (2005){ TA \l "Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc., 395 F.3d 1364 (Fed.Cir. 2005), *reh'g and reh'g en banc denied*, 405 F.3d 1388, *cert. denied*, 126 S.Ct. 488 (2005)" \s "Merck v. Teva, 395 F.3d 1364" \c 1 }. Merck's suit against Teva for relief from the prior judgment was C.A. No. 06-310 (GMS) (D.Del.).

82. On June 27, 2006, Teva filed a motion for sanctions under Rule 11 of the Federal Rules of Civil Procedure in the C.A. No. 06-310 case.

83. On June 30, 2006, Merck dismissed its case (C.A. No. 06-310) against Teva without responding to Teva's Rule 11 motion.

84. Merck's capitulation to the Rule 11 motion proves that Merck has known since October 2005 that it has had no objectively reasonable basis for asserting the '329 patent against anyone for filing an ANDA for alendronate sodium, including Apotex.

85. Had Merck's unjustified Rule 60(b) suit against Teva succeeded and the prior judgment vacated, it is likely that Teva's entry into the market for generic alendronate sodium would have been delayed beyond February 6, 2008, thus delaying the "market entry" triggering event of Teva's 180 day exclusivity period.

#### **MERCK'S ANTI-COMPETITIVE SCHEME**

86. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support for the proposition that Merck does not want to trigger the 180-day exclusivity period because it wants to limit the number of generic competitors that it will have to compete with when the exclusivity for its '077 patent expires.

87. If there is a triggering event at least 180 days prior to February 6, 2008 (i.e. by at least August 6, 2007), then all the subsequent generic filers can market their generic drugs at the same time on February 6, 2008 and Merck would then have to compete with a number of generics rather than just the first generic filer(s).

88. Recent history has shown that brand name drug companies will compete with the first generic by offering their own generic product.

89. The fewer the generic competitors in the market, the higher the price of the drug will be able to be maintained.

90. During the 180-day exclusivity period, the first generic to enter the market usually charges about 70% to 80% of the price of the brand name drug. Once several generic firms are allowed to enter the price drops to around 30% of the brand name drug's original price.

91. The first generic firm to enter the market usually obtains a large portion of the generic market.

92. A generic firm that does not enter the generic market when it first opens is severely disadvantaged because it has to compete with companies that have already recovered all or most of the costs of market entry during a period when the price was maintained at 70% to 80% of the brand price.

93. It is difficult to dislodge an established low-cost provider for an established market.

94. The fact that it is difficult to dislodge an established low-cost provider for a market constitutes a barrier to entry to other would-be low cost providers for that market.

95. If allowed to restrict the number of companies in the market, Merck will be able to transform a large portion of its brand market for Fosamax® into sales of its own generic alendronate sodium.

96. Merck's practice of filing patent infringement lawsuits against the secondary generic filers for alendronate sodium, including Apotex and Watson, and the ensuing use of covenants not to sue, is intended to eliminate Apotex and the other secondary generic filers from the market for at least the first 180 days after the first generic enters the market.

97. Merck's practice of filing patent infringement lawsuits against the secondary generic filers for alendronate sodium, and the ensuing use of covenants not to sue, is illegal because it is, in effect, an attempt to monopolize the market by keeping Apotex and other secondary generic filers out of the market in restraint of trade.

#### **RELEVANT MARKET**

98. The relevant geographic market in this case is the United States.

99. The relevant product market in this case is alendronate sodium tablets for use in the treatment of osteoporosis and Paget's disease.

100. Alendronate sodium is a unique molecule that is protected by Merck's '077 patent.

101. Merck is currently the only entity in the United States marketing any form of alendronate sodium for use in the treatment of osteoporosis and Paget's disease.

102. Alendronate sodium has unique benefits and advantages over other treatments for osteoporosis and Paget's disease.

103. Merck controls one hundred (100%) of the relevant market.

104. Merck has monopoly power in the relevant market through, *inter alia*, its ability to raise and/or control prices and/or exclude competition and/or restrict output without losing substantial business.

105. There are no reasonably interchangeable substitutes for alendronate sodium when prescribed for use in the treatment of osteoporosis or Paget's disease.

106. There are substantial barriers to entry into the relevant market including regulatory requirements.

#### **ANTITRUST INJURY**

107. Apotex produces more than 260 generic pharmaceuticals in over 4000 dosages and formats to over 115 countries around the world.

108. Apotex expended considerable effort and resources to develop a generic version of alendronate sodium that was therapeutically equivalent or bio-equivalent to Merck's Fosamax®.

109. Apotex currently sells a generic form of 70 mg alendronate sodium in Canada.

110. By filing a substantially complete ANDA for alendronate sodium with the FDA, Apotex has taken all actions necessary to obtain FDA approval of its ANDA for alendronate sodium for sale in the United States.

111. The FDA will likely grant tentative approval of Apotex's ANDA for alendronate sodium once the FDA's review of its application is completed. The FDA will likely grant final approval of Apotex's ANDA for alendronate sodium, and Apotex has no reason to believe that the FDA will not grant final approval, once the 30 month stay expires or is terminated, and the 180 day exclusivity period of the first generic applicant expires.

112. Upon receiving final approval of its ANDA for alendronate sodium from the FDA, Apotex intends to and is prepared to enter the U.S. market for generic alendronate sodium.

113. Merck's anti-competitive acts, including those set forth above, have a dangerous probability of harming competition and causing injury to Apotex by preventing the FDA from giving Apotex final approval to market its alendronate sodium drug product as a therapeutic equivalent to Merck's Fosamax® until the expiration of the 30 month stay or until the first generic filer enters the market, whichever is later.

114. But for Merck's anti-competitive acts, including presenting Apotex with the sham covenant not to sue, Apotex would likely be able to obtain a court decision finding the patents asserted by Merck to be invalid and/or not infringed, which decision would terminate the 30 month stay and trigger the 180 day exclusivity period of the first



generic filer, thus allowing Apotex and any other secondary generic applicants to enter the market for generic alendronate sodium on February 6, 2008, the same time as the first generic applicant(s) can enter the market.

115. Merck's anti-competitive acts, including those set forth above, will cause injury to Apotex by delaying its entry into the generic market for alendronate sodium for at least the first 180 days, thus allowing the first generic applicant(s), as well as Merck's own generic version, to establish market shares, and allowing the first generic applicant(s) to make excessive profits before prices fall once the secondary generic manufacturers are allowed to enter the market. Apotex and the other secondary generics will thereby be at a competitive disadvantage as compared to the first generic applicant(s).

116. Merck's anti-competitive acts, including those set forth above, will also cause injury to consumers who will pay higher prices for the generic version of alendronate sodium during the first 180 days after the first generic applicant(s) enters the market because Apotex and other secondary generic manufacturers will be prevented from entering the market during that 180 day period.

#### **COUNT I – DECLARATORY RELIEF**

117. Apotex repeats, realleges and incorporates by reference each of the allegations of paragraphs 1 through 116 as if set forth fully herein.

118. The relevant claims in the '329, '801, and '294 patents are invalid for at least the reasons set forth in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005).

119. Apotex cannot be held liable for infringement of the '941 patent at least because the claims of this patent are limited to a composition comprising excipients consisting essentially of anhydrous lactose, microcrystalline cellulose, croscarmellose sodium, and magnesium stearate; whereas, Apotex's tablets will not comprise lactose (either anhydrous or hydrous) or croscarmellose sodium, but will comprise as excipients only manitol, microcrystalline cellulose and magnesium stearate.

120. Apotex cannot be held liable for infringement of the '590, '410, and '004 patents at least because the claims of those patents are limited to a tablet comprising a diluent selected from anhydrous lactose and hydrous fast flow lactose; whereas, Apotex's tablets will not comprise anhydrous lactose or hydrous fast flow lactose.

121. Apotex cannot be held liable for infringement of the '726 and '207 patents at least because the claims of those patents are limited to anhydrous alendronate sodium; whereas, Apotex's tablets will not contain anhydrous alendronate sodium.

122. As a consequence of the foregoing, there exists a justiciable controversy as to whether the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents are valid and/or infringed. Apotex is entitled to a declaration that the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents are invalid and/or not infringed by the products that are the subject of Apotex's ANDA for alendronate sodium.

#### **COUNT II - ATTEMPTED MONOPOLIZATION**

123. Apotex repeats, realleges and incorporates by reference each of the allegations of paragraphs 1 through 122 as if set forth fully herein.

124. This Counterclaim arises under the Antitrust Laws of the United States, particularly the Sherman Antitrust Act, 15 U.S.C. §2.

125. Merck has engaged in a pattern and practice of anti-competitive conduct with the intent of preventing or delaying Apotex from marketing a competing alendronate sodium product for use in the treatment of osteoporosis and Paget's disease.

126. Such unlawful conduct includes, *inter alia*, creating barriers to competition; initiating sham litigation against Apotex on the nine patents in suit; presenting Apotex with a covenant not to sue and seeking to dismiss this case in order to avoid an adverse judgment on the merits that would terminate the 30 month stay and create a "court decision" triggering event of the first generic applicant's 180 day exclusivity period; and thereby unlawfully attempting to keep Apotex out of the market for generic alendronate sodium longer than it would otherwise.

127. Merck has engaged in anticompetitive conduct with the specific intent to monopolize and preserve a monopoly for alendronate sodium in the United States.

128. Merck, with full knowledge that the claims of the nine patents asserted in this action against Apotex were either invalid or not infringed by Apotex's proposed alendronate sodium product, deliberately impeded, and continued to deliberately impede, Apotex's efforts to bring its alendronate sodium product to market, including by bringing a baseless infringement action against Apotex for the nine patents at issue, and then presenting Apotex with a covenant not to sue in order to avoid an adverse decision on the merits. Merck brought its baseless action to attempt to monopolize the alendronate sodium market, and for the purpose of eliminating Apotex from competing in this market.

129. As evidenced by its actions with Watson, there is a dangerous probability of Merck's achieving monopoly power through the above-described scheme.

130. The Federal Circuit has steadfastly ruled that there is no reasonable apprehension of suit when a declaratory judgment plaintiff is presented with a covenant not to sue. Unless the Federal Circuit's "reasonable apprehension" test for an actual case or controversy is overruled by the Supreme Court, Merck will continue to be able to file objectively baseless lawsuits, which activate the 30 month stays, and avoid a court decision on the merits that would terminate the 30 month stays by presenting covenants not to sue.

131. Through such conduct Merck is also able to avoid triggering the first generic applicant's 180 day period of exclusivity and thereby limit competition for as long as possible.

**DEMAND FOR JUDGMENT AND PRAYER FOR RELIEF**

WHEREFORE, Apotex prays for judgment:

- A. Finding the '941, '590, '726, '207, '410, '004 '329, '801, and '294 patents invalid and/or not infringed;
- B. Finding that this is an exceptional case under 35 U.S.C. § 285;
- C. Awarding Apotex treble its actual damages incurred by Merck's violation of the antitrust laws;
- D. Awarding Apotex injunctive relief prohibiting Merck from engaging in the unlawful acts alleged in this Counterclaim;
- E. Awarding to Apotex its costs, expenses, and reasonable attorney's fees;
- F. Awarding such other relief as the Court deems just and appropriate.

**JURY DEMAND**

Apotex demands trial by jury for all issues triable by jury.

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*Attorneys for Defendant Apotex, Inc.*

759887 / 30234

# **EXHIBIT B**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

MERCK & CO., INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 06-230 (GMS)
	)	
APOTEX, INC.	)	<b>JURY TRIAL DEMANDED</b>
	)	
Defendant.	)	

**DEFENDANT APOTEX, INC.'S CORRECTED FIRST AMENDED  
ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendant, Apotex, Inc. ("Defendant" or "Apotex"), for its First Amended Answer, Affirmative Defenses, and Counterclaim, to the complaint of Merck & Co., Inc. ("Plaintiff" or "Merck"), states and alleges as follows:

**THE PARTIES**

1. Plaintiff Merck is a corporation incorporated under the laws of New Jersey with its principal place of business at One Merck drive, Whitehouse Station, New Jersey 08889.

**ANSWER:** Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore denies same.

2. On information and belief, Defendant Apotex, Inc. ("Apotex") is a Canadian company with offices at 150 Signet Drive, Toronto, Canada M9L 1T9. It has authorized Apotex Corp., incorporated under the laws of Delaware and with principal place of business at 2400 North Commerce Parkway, Suite 400 Weston, Florida 33326, to act as agent for service of process with respect to commencement of this patent infringement action.

**ANSWER:** Admitted.

**JURISDICTION AND VENUE**

3. This action arises under the patent laws of the United States of America and jurisdiction is founded on Title 28, United States Code §§ 1331 and 1338(a).

**ANSWER:** Apotex admits that Merck purports to bring an action under the patent laws of the United States of America and admits that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a); otherwise denied.

4. Venue is proper in this court under Title 28, United States Code §§ 1391(c) and 1400(b), because the defendant has submitted to personal jurisdiction in this judicial district for this action.

**ANSWER:** Admitted.

### **BACKGROUND**

5. On October 25, 1994, United States Letters Patent No. 5,358,941 (the “‘941 patent”), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS WITH LACTOSE, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The ‘941 patent is currently set to expire on December 2, 2012. The ‘941 patent discloses and claims novel pharmaceutical compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget’s disease, malignant hypercalcemia, and metastatic bone disease. A copy of the ‘941 patent is attached to this Complaint as Exhibit 1.

**ANSWER:** Apotex admits that United States Patent No. 5,358,941, entitled “Dry Mix Formulation For Bisphosphonic Acids With Lactose” was issued by the United States Patent and Trademark Office on October 25, 1994 to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare, and that a copy of the ‘941 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

6. On October 28, 1997, United States Letters Patent No. 5,681,590 (the “‘590 patent”), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The ‘590 patent is currently set to expire on December 2, 2012. The ‘590 patent discloses and claims novel pharmaceutical compositions and novel processes for manufacturing compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget’s disease, malignant



hypercalcemia, and metastatic bone disease. A copy of the '590 patent is attached to this Complaint as Exhibit 2.

**ANSWER:** Apotex admits that United States Patent No. 5,681,590, entitled "Dry Mix Formulation For Bisphosphonic Acids" was issued by the United States Patent and Trademark Office on October 28, 1997 to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare, and that a copy of the '590 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

7. On December 15, 1998, United States Letters Patent No. 5,849,726 (the "'726 patent"), entitled ANHYDROUS ALENDRONATE MONOSIDUM SALT FORMULATIONS, duly and legally issued to Gerald S. Brenner, Drazen Ostovic, Earl R. Oberholtzer, Jr., and J. Eric Thies. The '726 patent is currently set to expire on June 6, 2015. The '726 patent discloses and claims novel pharmaceutical compositions of anhydrous 4-amino-1-hydroxy-butyldiene-1, 1-bisphosphonic acid monosodium salt, as well as novel methods for treating and preventing bone loss with these compositions. A copy of the '726 patent is attached to this Complaint as Exhibit 3.

**ANSWER:** Apotex admits that United States Patent No. 5,849,726, entitled "Anhydrous Alendronate Monosidum Salt Formulations" was issued by the United States Patent and Trademark Office on December 15, 1998 to Gerald S. Brenner, Drazen Ostovic, Earl R. Oberholtzer, Jr., and J. Eric Thies, and that a copy of the '726 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

8. On December 28, 1999, United States Letters Patent No. 6,008,207 (the "'207 patent"), entitled ANHYDROUS ALENDRONATE MONOSIDUM SALT FORMULATIONS, duly and legally issued to Gerald S. Brenner, Drazen Ostovic, Earl R. Oberholtzer, Jr., and J. Eric Thies. The '207 patent is currently set to expire on June 6, 2015. The '207 patent discloses and claims novel methods for administering anhydrous

alendronate monosodium salt formulations. A copy of the '207 patent is attached to this Complaint as Exhibit 4.

**ANSWER:** Apotex admits that United States Patent No. 6,008,207, entitled "Anhydrous Alendronate Monosodium Salt Formulations" was issued by the United States Patent and Trademark Office on December 28, 1999 to Gerald S. Brenner, Drazen Ostovic, Earl R. Oberholtzer, Jr., and J. Eric Thies, and that a copy of the '207 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

9. On July 18, 2000, United States Letters Patent No. 6,090,410 (the "'410 patent"), entitled ANHYDROUS ALENDRONATE MONOSIDUM SALT FORMULATIONS, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The '410 patent is currently set to expire on December 2, 2012. The '410 patent discloses and claims novel pharmaceutical compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget's disease, malignant hypercalcemia, and metastatic bone disease. A copy of the '410 patent is attached to this Complaint as Exhibit 5.

**ANSWER:** Apotex admits that United States Patent No. 6,090,410, entitled "Anhydrous Alendronate Monosodium Salt Formulations" was issued by the United States Patent and Trademark Office on July 18, 2000 to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare, and that a copy of the '410 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

10. On February 27, 2001, United States Letters Patent No. 6,194,004 (the "'004 patent"), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The '004 patent is currently set to expire on December 2, 2012. The '004 patent discloses and claims novel pharmaceutical compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis,

Paget's disease, malignant hypercalcemia, and metastatic bone disease. A copy of the '004 patent is attached to this Complaint as Exhibit 6.

**ANSWER:** Apotex admits that United States Patent No. 6,194,004, entitled "Dry Mix Formulation For Bisphosphonic Acids" was issued by the United States Patent and Trademark Office on February 27, 2001 to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare, and that a copy of the '004 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

11. On November 30, 1999, United States Letters Patent No. 5,994,329 (the "'329 patent") duly and legally issued to Anastasia G. Daifotis, Arthur C. Santora, II, and John Yates entitled METHOD FOR INHIBITING BONE RESORPTION. The '329 patent is currently set to expire on July 17, 2018. The '329 patent discloses and claims methods for inhibiting bone resorption in mammals while minimizing the occurrence of or potential for adverse gastrointestinal effects, and pharmaceutical compositions and kits for carrying out these therapeutic methods. A copy of the '329 patent is attached to this Complaint as Exhibit 7.

**ANSWER:** Apotex admits that United States Patent No. 5,994,329, entitled "Method For Inhibiting Bone Resorption" was issued by the United States Patent and Trademark Office on November 30, 1999 to Anastasia G. Daifotis, Arthur C. Santora, II, and John Yates, and that a copy of the '329 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

12. On January 18, 2000, United States Letters Patent No. 6,015,801 (the "'801 patent") duly and legally issued to Anastasia G. Daifotis, A. John Yates, and Arthur C. Santora, II entitled METHOD OF INHIBITING BONE RESORPTION. The '801 patent is currently set to expire on July 17, 2018. The '801 patent discloses and claims methods for inhibiting bone resorption in mammals while minimizing the occurrence of or potential for adverse gastrointestinal effects, and pharmaceutical

compositions and kits for carrying out these therapeutic methods. A copy of the '801 patent is attached to this Complaint as Exhibit 8.

**ANSWER:** Apotex admits that United States Patent No. 6,015,801, entitled "Method Of Inhibiting Bone Resorption" was issued by the United States Patent and Trademark Office on January 18, 2000 to Anastasia G. Daifotis, A. John Yates, and Arthur C. Santora, II, and that a copy of the '801 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

13. On May 1, 2001, United States Letters Patent No. 6,225,294 (the "'294 patent") duly and legally issued to Anastasia G. Daifotis, Arthur C. Santora, II and John Yates entitled METHOD OF INHIBITING BONE RESORPTION. The '294 patent is currently set to expire July 17, 2018. The '294 patent discloses and claims methods for inhibiting bone resorption in mammals while minimizing the occurrence of or potential for adverse gastrointestinal effects, and pharmaceutical compositions and kits for carrying out these therapeutic methods. A copy of the '294 patent is attached to this Complaint as Exhibit 9.

**ANSWER:** Apotex admits that United States Patent No. 6,225,294, entitled "Method Of Inhibiting Bone Resorption" was issued by the United States Patent and Trademark Office on May 1, 2001 to Anastasia G. Daifotis, Arthur C. Santora, II, and John Yates, and that a copy of the '294 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

14. Merck is the owner through assignment of the '941, '590, '726, '207, '410, '004, '329, '801 and '294 patents. Merck also owns an approved New Drug Application (NDA No. 20-560) for alendronate sodium tablets that are sold under its trademark FOSAMAX®.

**ANSWER:** Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore denies same.

15. The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration ("FDA") under the Federal Food, Drug, and Cosmetic Act. Merck listed the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents in the Orange Book for its FOSAMAX® tablets.

**ANSWER:** Apotex admits that the '941, '590, '726, '207, '410, '004, '329, '801, '801, and '294 patents are listed in the "Orange Book" for Fosamx Fosamax® tablets and denies the truth of the remaining averments in this paragraph.

16. The FDA granted a six-month period of market exclusivity beyond the patent terms for Merck's FOSAMAX® drug product due to the timely submission and acceptance of pediatric studies pursuant to 21 U.S.C. § 355a(c). This six-month period is also listed in the Orange Book. The FDA may therefore not approve to market generic versions of Merck's FOSAMAX® tablets until six months after the expiration date of the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents. The six-month "pediatric exclusivity period" expires on June 2, 2013, for the '941 patent; June 2, 2013, for the '590 patent; December 6, 2015, for the '726 patent; December 6, 2015, for the '207 patent; June 2, 2013, for the '410 patent; June 2, 2013, for the '004 patent; January 17, 2019, for the '329 patent; January 17, 2019, for the '801 patent; and January 17, 2019, for the '294 patent. The FDA also may not approve to market generic versions of Merck's FOSAMAX® tablets until the expiration of all other patents and the subsequent pediatric exclusivity period listed in the Orange Book.

**ANSWER:** Apotex admits that the Orange Book shows the pediatric exclusivity period for the patents as stated in the averments in this paragraph and Apotex denies the remaining averments in this paragraph.

17. On information and belief, an Abbreviated New Drug Application (ANDA No. 077-982) has been filed on behalf of Apotex, including a certification under Title 21, United States Code § 355(j)(2) with the FDA for 5 mg, 10 mg, 35 mg, and 70 mg alendronate sodium tablets. Apotex's ANDA No. 077-982 allegedly contains a certification of invalidity, unenforceability, and/or noninfringement of the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents. Notice of that certification, but not the certification, was transmitted to Merck on or after February 24, 2006.

**ANSWER:** Admitted.

18. On information and belief, Apotex filed ANDA No. 077-982 because it seeks to enter the market that FOSAMAX<sup>®</sup> pharmaceutical products have created due to their benefits and advantages.

**ANSWER:** Denied, ~~accept~~except to admit that Apotex seeks permission from the FDA to sell a generic version of Fosamax<sup>®</sup>.

**COUNT I**

19. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

**ANSWER:** Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

20. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '941 patent, before the expiration of the '941 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

21. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '941 patent, it was aware of the existence of the '941 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

**ANSWER:** Apotex admits it was aware of the '941 patent at the time it filed ANDA No. 077-982; otherwise denied.

22. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '941 patent.

**ANSWER:** Denied.

23. On information and belief, the infringement by Apotex of the '941 patent was and is willful.

**ANSWER:** Denied.

24. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

**ANSWER:** Denied.

## **COUNT II**

25. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

**ANSWER:** Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

26. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '590 patent, before the expiration of the '590 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

27. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '590 patent, it was aware of the existence of the '590 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

**ANSWER:** Apotex admits it was aware of the '590 patent at the time it filed ANDA No. 077-982; otherwise denied.

28. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '590 patent.

**ANSWER:** Denied.

29. On information and belief, the infringement by Apotex of the '590 patent was and is willful.

**ANSWER:** Denied.

30. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.



**ANSWER:** Denied.

**COUNT III**

31. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

**ANSWER:** Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

32. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '726 patent, before the expiration of the '726 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

33. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '726 patent, it was aware of the existence of the '726 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

**ANSWER:** Apotex admits it was aware of the '726 patent at the time it filed ANDA No. 077-982; otherwise denied.

34. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '726 patent.

**ANSWER:** Denied.

35. On information and belief, the infringement by Apotex of the '726 patent was and is willful.

**ANSWER:** Denied.

36. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

**ANSWER:** Denied.

**COUNT IV**

10 DeltaView comparison of PowerDocs://PAC/731355/1 and PowerDocs://PAC/759887/1. Performed on 11/3/2006.



37. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

**ANSWER:** Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

38. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '207 patent, before the expiration of the '207 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

39. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '207 patent, it was aware of the existence of the '207 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

**ANSWER:** Apotex admits it was aware of the '207 patent at the time it filed ANDA No. 077-982; otherwise denied.

40. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '207 patent.

**ANSWER:** Denied.

41. On information and belief, the infringement by Apotex of the '207 patent was and is willful.

**ANSWER:** Denied.

42. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

**ANSWER:** Denied.

#### **COUNT V**

43. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

**ANSWER:** Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

44. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '410 patent, before the expiration of the '410 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

45. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '410 patent, it was aware of the existence of the '410 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

**ANSWER:** Apotex admits it was aware of the '410 patent at the time it filed ANDA No. 077-982; otherwise denied.

46. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '410 patent.

**ANSWER:** Denied.

47. On information and belief, the infringement by Apotex of the '410 patent was and is willful.

**ANSWER:** Denied.

48. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

**ANSWER:** Denied.

#### **COUNT VI**

49. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

**ANSWER:** Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

50. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '004 patent, before the expiration of the '004 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

51. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '004 patent, it was aware of the existence of the '004 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

**ANSWER:** Apotex admits it was aware of the '004 patent at the time it filed ANDA No. 077-982; otherwise denied.

52. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '004 patent.

**ANSWER:** Denied.

53. On information and belief, the infringement by Apotex of the '004 patent was and is willful.

**ANSWER:** Denied.

54. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

**ANSWER:** Denied.

## **COUNT VII**

55. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

**ANSWER:** Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

56. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '329 patent,

before the expiration of the '329 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

57. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '329 patent, it was aware of the existence of the '329 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

**ANSWER:** Apotex admits it was aware of the '329 patent at the time it filed ANDA No. 077-982; otherwise denied.

58. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '329 patent.

**ANSWER:** Denied.

59. On information and belief, the infringement by Apotex of the '329 patent was and is willful.

**ANSWER:** Denied.

60. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

**ANSWER:** Denied.

### **COUNT VIII**

61. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

**ANSWER:** Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

62. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use or sale of a drug product the use of which is claimed in the '801 patent, before the expiration of the '801 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

63. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '801 patent, it was aware of the existence of the '801 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

**ANSWER:** Apotex admits it was aware of the '801 patent at the time it filed ANDA No. 077-982; otherwise denied.

64. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '801 patent.

**ANSWER:** Denied.

65. On information and belief, the infringement by Apotex of the '801 patent was and is willful.

**ANSWER:** Denied.

66. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

**ANSWER:** Denied.

### **COUNT IX**

67. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

**ANSWER:** Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

68. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '294 patent, before the expiration of the '294 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

69. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '294 patent, it was aware of the existence of the '294 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

**ANSWER:** Apotex admits it was aware of the '294 patent at the time it filed ANDA No. 077-982; otherwise denied.

70. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '294 patent.

**ANSWER:** Denied.

71. On information and belief, the infringement by Apotex of the '294 patent was and is willful.

**ANSWER:** Denied.

72. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

**ANSWER:** Denied.

WHEREFORE, Defendant prays that Plaintiff take nothing from this action and its complaint be dismissed with prejudice, with costs assessed against Plaintiff.

### **AFFIRMATIVE DEFENSES**

#### **First Affirmative Defense**

The complaint and each Count thereof fails to state a claim upon which relief can be granted.

#### **Second Affirmative Defense**

After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents are invalid and/or unenforceable for failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

#### **Third Affirmative Defense**

Merck is collaterally estopped from asserting the validity of the '329 patent against Apotex by virtue of the final decision of the United States Court of Appeals for the Federal Circuit in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed.Cir. 2005), *reh'g and reh'g en banc denied*, 405 F.3d 1388, *cert. denied*, 126 S.Ct. 488 (2005), which invalidated the relevant claims of that patent{  
TA \l "Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.,  
395 F.3d 1364 (Fed.Cir. 2005), *reh'g and reh'g en banc denied*, 405 F.3d 1388, *cert. denied*, 126 S.Ct. 488 (2005)" \s "Merck v. Teva, 395 F.3d 1364" \c 1 }.

#### Fourth Affirmative Defense

Merck is collaterally estopped from asserting the validity of the '801 patent against Apotex by virtue of the final decision of the United States Court of Appeals for the Federal Circuit in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed.Cir. 2005), *reh'g and reh'g en banc denied*, 405 F.3d 1388, *cert. denied*, 126 S.Ct. 488 (2005), which prevents Merck from asserting the validity of the relevant claims of that patent.

#### Fifth Affirmative Defense

Merck is collaterally estopped from asserting the validity of the '294 patent against Apotex by virtue of the final decision of the United States Court of Appeals for the Federal Circuit in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed.Cir. 2005), *reh'g and reh'g en banc denied*, 405 F.3d 1388, *cert. denied*, 126 S.Ct. 488 (2005), which prevents Merck from asserting the validity of the relevant claims of that patent.

## COUNTERCLAIM

Counterclaimant Apotex, Inc. ("Apotex") for its counterclaim against counter-defendant Merck & Co., Inc. ("Merck") alleges as follows:

### NATURE OF THE ACTION

1. Apotex's claims arise out of Merck's anti-competitive scheme of filing infringement suits it knows, or should know, are baseless and then presenting the alleged infringer with a covenant not to sue in order to avoid an adverse decision on the merits with the intent of preventing or delaying Apotex and other secondary generic applicants from marketing a generic version of alendronate sodium that would compete with Merck's highly lucrative brand version called Fosamax®, used in the treatment and prevention of osteoporosis and Paget's disease.

### PARTIES AND JURISDICTION

2. 1. Counterclaimant Apotex, Inc. ("Apotex") is a Canadian company with offices at 150 Signet Drive, Toronto, Canada M9L 1T9.

3. 2. On information and belief, counterdefendant Merck, Inc. ("Merck") is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

3. —

4. This Counterclaim arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355) (hereinafter "Hatch-Waxman Amendments"), and the



Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066{ TA \l "117 Stat. 2066 (2003)" \s "117 Stat. 2066" \c 2 } (2003) (hereinafter "MMA"); the Antitrust Laws of the United States, particularly the Sherman Antitrust Act, 15 U.S.C. § 2; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. This Court has subject matter jurisdiction under the patent laws, Title 35 of the U.S. Code; The Declaratory Judgment Act, 28 U.S.C. § 2201; and 28 U.S.C. § 1338 over this Counterclaim pursuant to 28 U.S.C. §§ 1331, 1332, 1337, 1338(a), and 2201.

6. 4. Venue and personal jurisdiction are proper in this district because the counterdefendant Merck, *inter alia*, is subject to personal jurisdiction in this judicial district and has submitted itself to the jurisdiction of this Court.

#### HATCH-WAXMAN SCHEME

7. The Hatch-Waxman Amendments established a simplified procedure for FDA approval of generic drugs in order to make low cost generic drugs more available.

8. The FDA must approve all drugs before they can be introduced in interstate commerce.

9. Under the Hatch-Waxman Amendments, a manufacturer that seeks to market a generic drug may submit an Abbreviated New Drug Application ("ANDA") for approval by the FDA, rather than submitting a New Drug Application ("NDA") concerning the safety and efficacy of the generic drug, and it may rely on safety and efficacy studies previously submitted by the pioneer

manufacturer by submitting information showing the generic drug's bioequivalence with the previously approved drug product.

10. Also under the Hatch-Waxman Amendments, a pioneer drug manufacturer that holds an approved NDA is required to notify the FDA of all patents that claim the drug for which the NDA applicant submitted the application. The FDA lists such patents related to a specific drug in its "Approved Drug Products With Therapeutic Equivalence Evaluations" (otherwise known as the "Orange Book").

11. As part of the approval process, an ANDA applicant must make a certification addressing each patent listed in the Orange Book that claims the drug.

12. More specifically, the applicant must certify that (I) no such patent information has been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is submitted. These are commonly referred to as paragraph I, II, III, and IV certifications.

13. When an ANDA contains a paragraph IV certification, the generic manufacturer must give notice to the patentee and the NDA holder and provide a detailed basis for its belief that the patent is not infringed, invalid, or unenforceable.

14. Under the Hatch-Waxman Amendments, making a paragraph IV certification is an act of infringement.

15. Upon receipt of a paragraph IV certification, the patentee then has forty-five days to sue the generic manufacturer for patent infringement.

16. If the patentee does not file an infringement suit within forty-five days of receiving a paragraph IV notification, the FDA may approve the ANDA once all FDA exclusivities have expired and the FDA determines that the proposed generic is bioequivalent to the approved drug and is otherwise approvable.

17. If the patentee does file an infringement action, FDA approval is automatically stayed for thirty months, or until the court hearing the infringement case determines that the patent(s) is invalid, not infringed, or unenforceable, or the patent(s) expires, whichever is earlier.

18. The first ANDA holder (first generic filer) to file a paragraph IV certification is entitled to a 180-day period of exclusivity, during which time the FDA will not approve any other ANDAs containing paragraph IV certifications that list the same pioneer drug.

19. The 180-day exclusivity period does not begin to run until the first generic filer markets the drug or there is a decision by the court (in a suit against any generic manufacturer who makes a paragraph IV certification for the drug at issue) finding that the patent(s) listed in the Orange Book are either invalid or not infringed, whichever is earlier.

MERCK'S PATENTS RELATING TO FOSAMAX®

20. Merck is the owner of a number of patents listed in the Orange Book for the drug alendronate sodium, which is sold by Merck under the trademark Fosamax®.

21. Launched in 1995, Fosamax® is used for the treatment and prevention of osteoporosis and for the treatment of Paget's disease.

22. Fosamax® was Merck's second largest selling drug in 2005, with nearly \$3.2 billion in sales worldwide.

23. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Fosamax® is a vitally important component in Merck's drug portfolio and Merck is interested in maintaining its market share and profits for as long as it can.

24. Currently, Merck's market share is protected by its patents covering Fosamax® that are listed in the Orange Book.

25. The active ingredient in Fosamax® is alendronate sodium. Merck's patent on this active ingredient is U.S. Pat. No. 4,621,077 ("the '077 patent").

26. The '077 patent is set to expire on August 6, 2007, but Merck has an additional FDA exclusivity until February 6, 2008.

27. The '077 patent was found valid in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 228 F.Supp.2d 480 (D.Del. 2002), *aff'd*, 347 F.3d 1367 (Fed.Cir. 2003){ TA \l "Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc., 228 F.Supp.2d 480 (D.Del. 2002), *aff'd*, 347 F.3d 1367 (Fed.Cir. 2003)" \s "Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc., 228 F.Supp.2d 480 (D.Del. 2002), *aff'd*, 347 F.3d 1367 (Fed.Cir. 2003)" \c 1 }.

28. Merck also has a number of other patents that it is using to extend its monopoly of alendronate sodium. These patents relate, however, to various formulations of the active ingredient and to dosage strategies.

29. The patents directed to the alendronate sodium formulations that Merck asserted in its complaint are: U.S. Patent Nos. 5,358,941 ("the '941 patent"),

5,681,590 (“the ‘590’ patent”), 5,894,726 (“the ‘726 patent”), 6,008,207 (“the ‘207 patent”), 6,090,410 (“the ‘410 patent”) and 6,194,004 (“the ‘004 patent”). The patents directed to the dosage regimens asserted in the complaint are: U.S. Patent Nos. 5,994,329 (“the ‘329 patent”), 6,015,801 (“the ‘801 patent”), and 6,225,294 (“the ‘294 patent”).

30. The ‘941, ‘590, ‘410, and ‘004 patents are currently set to expire on December 2, 2012; the ‘726 and ‘207 patents are currently set to expire on June 6, 2015; and the ‘329, ‘801, and ‘294 patents are currently set to expire on July 7, 2018. Each of these patents has an additional six months of FDA exclusivity beyond the patent expiration dates though.

#### MERCK’S PRE-SUIT KNOWLEDGE

31. Apotex filed an ANDA seeking approval for a generic version of alendronate sodium.

32. On February 24, 2006, Apotex provided its paragraph IV certification to Merck, notifying Merck that it had filed an ANDA for alendronate sodium and that, other than the ‘077 patent, the patents listed by Merck in the Orange Book for alendronate sodium, i.e., the nine patents that are at issue in this case, were either invalid, unenforceable, and/or not infringed.

33. Specifically, Apotex told Merck that the ‘329 and ‘801 patents were invalid based upon a prior court decision which held that two claims of the ‘329 patent were invalid.

34. Apotex also told Merck that its ANDA did not infringe Merck’s ‘941 patent at least because the claims of that patent are limited to a composition

comprising anhydrous lactose, among other things, and Apotex's alendronate sodium tablets will not contain lactose (either anhydrous or hydrous).

35. Apotex further told Merck that the '590, '410, and '004 patents were not infringed by its ANDA because the claims of those patents were limited to a tablet containing either anhydrous lactose or hydrous fast flow lactose, and Apotex's tablets would not contain anhydrous lactose or hydrous fast flow lactose.

36. Apotex also told Merck that its ANDA would not infringe the '726, '207, and '294 patents because the claims of those patents were limited to anhydrous alendronate sodium, whereas, Apotex's tablets would not contain anhydrous alendronate sodium.<sup>1</sup>

37. Apotex made a paragraph III certification in its ANDA with respect to the '077 patent certifying that it would not market its generic version until the expiration of the '077 patent and its pediatric exclusivity, which were set to expire on February 6, 2008.

38. As required under the Hatch-Waxman scheme, Apotex offered in its paragraph IV certification to provide Merck with certain confidential information in order for Merck to determine whether Apotex's ANDA did in fact infringe Merck's patents, notwithstanding Apotex's paragraph IV certification, prior to Merck's filing an infringement lawsuit.

39. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that, prior to filing its infringement suit

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<sup>1</sup> The '294 patent was mistakenly included with this set of patents when it should have been included with the '329 and '801 dosage patents. This mistake, however, should have been obvious to Merck because the '294 patent is a continuation of the application which became the '329 patent.



against Apotex, Merck knew it was within the ability of one of ordinary skill in formulating and manufacturing medications to make generic alendronate sodium tablets without using lactose (hydrous, anhydrous, or fast-flowing).

40. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that, prior to filing its infringement suit against Apotex, Merck knew it was within the ability of one of ordinary skill in formulating and manufacturing medications to make generic alendronate sodium tablets by using hydrous alendronate sodium instead of anhydrous alendronate sodium.

41. On January 28, 2005, the Federal Circuit reversed the lower court and held that claims 23 and 37 of Merck's '329 patent relating to the once-weekly dosage of alendronate sodium were invalid as obvious. See Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc., 395 F.3d 1364 (Fed.Cir. 2005), reh'g and reh'g en banc denied, 405 F.3d 1388, cert. denied, 126 S.Ct. 488 (2005)} TA \l "Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc., 395 F.3d 1364 (Fed.Cir. 2005), reh'g and reh'g en banc denied, 405 F.3d 1388, cert. denied, 126 S.Ct. 488 (2005)" \s "Merck v. Teva, 395 F.3d 1364" \c 1 }. The Supreme Court denied Merck's petition for certiorari on October 17, 2005.

42. The '801 patent is related to the '329 patent in that it is a continuation-in-part of the same application of which the '329 is a continuation.

43. The '294 patent is related to the '329 patent in that it is a continuation of the application which became the '329 patent.

44. Merck knew prior to filing its infringement suit against Apotex, which asserts the '329 patent as well as the related dosage patents (the '801 and '294 patents), that its claims relating to the once-weekly dosage of alendronate sodium had been held invalid in a final, nonappealable decision.

45. Merck knew prior to filing its infringement suit against Apotex that the claims in the '329 patent related to alendronate sodium were invalid and unenforceable.

46. Merck knew prior to filing its infringement suit against Apotex that Merck had no objectively reasonable basis for believing that Apotex was infringing any valid claims of the patents that were the subject of Apotex's paragraph IV certification.

#### MERCK'S SUING OF APOTEX

47. Despite the foregoing, on April 7, 2006, Merck filed this patent infringement suit against Apotex.

48. Merck's filing of this lawsuit against Apotex imposed a 30 month stay, measured from Merck's receipt of Apotex's paragraph IV certifications, on the FDA's approval of Apotex's ANDA for alendronate sodium.

49. The 30 month stay will not expire until at least August 24, 2008, unless there is a court decision finding that the patents asserted in Apotex's paragraph IV certification are invalid or not infringed.

50. A dismissal of this case for lack of subject matter jurisdiction will not terminate the 30 month stay.



51. Thus, the filing of this lawsuit created a barrier to Apotex's entry into the market for generic alendronate sodium tablets.

52. The filing of this lawsuit was objectively baseless because Merck knew that the claims in the patents it was asserting were invalid and/or not infringed by Apotex's proposed alendronate sodium product as set forth in its ANDA.

53. The filing of this lawsuit was an objectively unreasonable effort by Merck to reduce competition in the market for generic alendronate sodium tablets.

54. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that Merck brought this lawsuit in bad faith, knowing that the patents it was asserting were invalid and/or not infringed by Apotex's alendronate sodium product as set forth in Apotex's ANDA, but intending to present a covenant not to sue so that it could avoid a court decision on the merits, thus maintaining the 30 month stay on Apotex's ANDA for alendronate sodium and avoiding a trigger of the 180 day exclusivity, all to keep Apotex out of the market longer than would be the case otherwise in order to maintain Merck's monopoly.

#### MERCK'S UNILATERAL COVENANT NOT TO SUE

55. After Merck filed its complaint against Apotex, Apotex subsequently provided Merck with certain confidential information from its ANDA in order to resolve this matter.

56. That information showed that Apotex does not use a formulation that is covered by Merck's formulation patents.

57. After Apotex provided its confidential information to Merck, Merck indicated that it would present Apotex with a covenant not to sue.

58. Merck refused to agree to any dismissal order in which the Court made any findings that Apotex did not infringe Merck's patents.

59. A decision by the court finding that all of Merck's listed patents are not infringed or invalid would terminate the automatic 30-month stay for FDA approval of Apotex's ANDA.

60. A court decision finding that all of Merck's listed patents are not infringed or invalid would also trigger the 180-day exclusivity period that is normally available to the first generic to file an ANDA, whether it has marketed the product or not.

61. On August 7, 2006, Merck unilaterally served on Apotex a covenant not to sue Apotex for infringement of any of the nine patents in suit based upon the importation, manufacture, use, sale, or offer for sale of the alendronate sodium tablets that are the subject of Apotex's ANDA for alendronate sodium.

62. Merck's unilaterally tendered covenant not to sue admits on its face that claims 23 and 37 of the '329 patent have been held invalid; and therefore could not be infringed.

63. Merck's unilaterally tendered covenant not to sue also admits on its face that based upon confidential information provided by Apotex the products that are the subject of Apotex's ANDA for alendronate sodium (1) will not contain anhydrous lactose or hydrous fast flow lactose, and (2) will not contain anhydrous alendronate sodium.

64. Merck's covenant not to sue Apotex for infringement of the nine patents in suit offers no protection to Apotex's potential customers against an infringement suit.

65. After serving Apotex with its covenant not to sue, Merck sought to dismiss its claims and Apotex's counterclaim for lack of subject matter jurisdiction.

66. A dismissal of this case based upon Merck's covenant not to sue will not terminate the 30 month stay, nor will it constitute a "court decision" triggering event for the 180 day exclusivity period.

67. Merck's covenant not to sue is a sham because Merck does not believe that Apotex's ANDA for alendronate sodium infringes any valid claims of Merck's patents in suit.

68. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support for the proposition that Merck's unjustified institution of this lawsuit was done with the intention of establishing a 30 month stay on Apotex's generic drug application for alendronate sodium with foreknowledge that Merck would tender a covenant not to sue to deprive this Court of jurisdiction, yet maintain the 30 month stay.

69. A reasonable opportunity for further investigation or discovery is likely to provide evidence that shows that Merck unilaterally tendered its covenant not to sue with the intention of maintaining the 30 month stay on Apotex's generic drug application for alendronate sodium, and avoiding the "court decision" triggering event for the 180 day exclusivity period of the first generic filer for alendronate sodium.

70. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support to show that Merck tendered its covenant not to sue knowing that Apotex did not infringe any valid claim of the patents in suit.

71. A reasonable opportunity for further investigation and discovery is likely to provide evidentiary support that Merck tendered its covenant not to sue Apotex because it knew that its patents were invalid or not infringed by Apotex, and that the covenant tendered is a sham created to fend off the inevitable judgment of invalidity and non-infringement.

72. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support for the proposition that absent Merck's use of a sham covenant not to sue, Apotex would have obtained a "court decision" finding the patents invalid or not infringed, which would have terminated the 30 month stay and triggered the first generic applicant's 180 day exclusivity period thereby allowing Apotex to enter the market for generic alendronate sodium drug product as a therapeutic equivalent to Fosamax® market in February 2008.

73. A "court decision" finding the patents invalid and/or not infringed would also protect Apotex's potential customers for alendronate sodium tablets.

#### MERCK'S SUIT AGAINST WATSON LABORATORIES

74. On September 7, 2005, Merck filed an infringement action in this district against Watson Laboratories, Inc. ("Watson") (Case No. 05-cv-00658 (GMS)), in which Merck alleged that Watson's ANDA for alendronate sodium infringed the same patents at issue in this case.

75. On October 19, 2005, Watson filed an answer and counterclaim. In its counterclaim, Watson sought a declaratory judgment that the patents asserted against it were either invalid or not infringed.

76. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support for the proposition that Merck subsequently presented Watson with an unsolicited covenant not to sue and then sought to dismiss the case and Watson's counterclaim for lack of subject matter jurisdiction.

77. Over Watson's objection, this Court subsequently dismissed Merck's infringement claim and Watson's counterclaim.

78. Merck was thus able to avoid a court decision triggering event in the Watson case, and as it stands now Watson is prevented from entering the market for generic alendronate sodium until 180 days after the first generic filer enters the market.

MERCK'S ACTIONS AGAINST TEVA PHARMACEUTICALS USA INC.

79. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support for the proposition that Teva Pharmaceuticals USA Inc. ("Teva") holds the position of the first to file an ANDA for alendronate sodium.

80. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support for the proposition that Teva may enter the market for generic alendronate sodium when Merck's exclusivity expires on February 6, 2008.

81. On May 10, 2006, Merck sued Teva for relief from the judgment entered by mandate of the United States Court of Appeals for the Federal Circuit in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, (No. 04-1005) as a result of Teva's fraud, misrepresentations, or other misconduct. That appellate judgment was a reversal of the judgment entered in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, (C.A. No. 01-048 (JJF) (D.Del.)). The Federal Circuit held that claims 23 and 37 of Merck's '329 patent relating to the once-weekly dosage of alendronate sodium were invalid as obvious. See *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed.Cir. 2005), *reh'g and reh'g en banc denied*, 405 F.3d 1388, *cert. denied*, 126 S.Ct. 488 (2005)} TA \l "*Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed.Cir. 2005), *reh'g and reh'g en banc denied*, 405 F.3d 1388, *cert. denied*, 126 S.Ct. 488 (2005)" \s "*Merck v. Teva*, 395 F.3d 1364" \c 1 }. Merck's suit against Teva for relief from the prior judgment was C.A. No. 06-310 (GMS) (D.Del.).

82. On June 27, 2006, Teva filed a motion for sanctions under Rule 11 of the Federal Rules of Civil Procedure in the C.A. No. 06-310 case.

83. On June 30, 2006, Merck dismissed its case (C.A. No. 06-310) against Teva without responding to Teva's Rule 11 motion.

84. Merck's capitulation to the Rule 11 motion proves that Merck has known since October 2005 that it has had no objectively reasonable basis for asserting the '329 patent against anyone for filing an ANDA for alendronate sodium, including Apotex,



85. Had Merck's unjustified Rule 60(b) suit against Teva succeeded and the prior judgment vacated, it is likely that Teva's entry into the market for generic alendronate sodium would have been delayed beyond February 6, 2008, thus delaying the "market entry" triggering event of Teva's 180 day exclusivity period.

MERCK'S ANTI-COMPETITIVE SCHEME

86. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support for the proposition that Merck does not want to trigger the 180-day exclusivity period because it wants to limit the number of generic competitors that it will have to compete with when the exclusivity for its '077 patent expires.

87. If there is a triggering event at least 180 days prior to February 6, 2008 (i.e. by at least August 6, 2007), then all the subsequent generic filers can market their generic drugs at the same time on February 6, 2008 and Merck would then have to compete with a number of generics rather than just the first generic filer(s).

88. Recent history has shown that brand name drug companies will compete with the first generic by offering their own generic product.

89. The fewer the generic competitors in the market, the higher the price of the drug will be able to be maintained.

90. During the 180-day exclusivity period, the first generic to enter the market usually charges about 70% to 80% of the price of the brand name drug. Once several generic firms are allowed to enter the price drops to around 30% of the brand name drug's original price.

91. The first generic firm to enter the market usually obtains a large portion of the generic market.

92. A generic firm that does not enter the generic market when it first opens is severely disadvantaged because it has to compete with companies that have already recovered all or most of the costs of market entry during a period when the price was maintained at 70% to 80% of the brand price.

93. It is difficult to dislodge an established low-cost provider for an established market.

94. The fact that it is difficult to dislodge an established low-cost provider for a market constitutes a barrier to entry to other would-be low cost providers for that market.

95. If allowed to restrict the number of companies in the market, Merck will be able to transform a large portion of its brand market for Fosamax® into sales of its own generic alendronate sodium.

96. Merck's practice of filing patent infringement lawsuits against the secondary generic filers for alendronate sodium, including Apotex and Watson, and the ensuing use of covenants not to sue, is intended to eliminate Apotex and the other secondary generic filers from the market for at least the first 180 days after the first generic enters the market.

97. Merck's practice of filing patent infringement lawsuits against the secondary generic filers for alendronate sodium, and the ensuing use of covenants not to sue, is illegal because it is, in effect, an attempt to monopolize the market by



keeping Apotex and other secondary generic filers out of the market in restraint of trade.

#### RELEVANT MARKET

98. The relevant geographic market in this case is the United States.

99. The relevant product market in this case is alendronate sodium tablets for use in the treatment of osteoporosis and Paget's disease.

100. Alendronate sodium is a unique molecule that is protected by Merck's '077 patent.

101. Merck is currently the only entity in the United States marketing any form of alendronate sodium for use in the treatment of osteoporosis and Paget's disease.

102. Alendronate sodium has unique benefits and advantages over other treatments for osteoporosis and Paget's disease.

103. Merck controls one hundred (100%) of the relevant market.

104. Merck has monopoly power in the relevant market through, *inter alia*, its ability to raise and/or control prices and/or exclude competition and/or restrict output without losing substantial business.

105. There are no reasonably interchangeable substitutes for alendronate sodium when prescribed for use in the treatment of osteoporosis or Paget's disease.

106. There are substantial barriers to entry into the relevant market including regulatory requirements.

#### ANTITRUST INJURY

107. Apotex produces more than 260 generic pharmaceuticals in over 4000 dosages and formats to over 115 countries around the world.

108. Apotex expended considerable effort and resources to develop a generic version of alendronate sodium that was therapeutically equivalent or bio-equivalent to Merck's Fosamax®.

109. Apotex currently sells a generic form of 70 mg alendronate sodium in Canada.

110. By filing a substantially complete ANDA for alendronate sodium with the FDA, Apotex has taken all actions necessary to obtain FDA approval of its ANDA for alendronate sodium for sale in the United States.

111. The FDA will likely grant tentative approval of Apotex's ANDA for alendronate sodium once the FDA's review of its application is completed. The FDA will likely grant final approval of Apotex's ANDA for alendronate sodium, and Apotex has no reason to believe that the FDA will not grant final approval, once the 30 month stay expires or is terminated, and the 180 day exclusivity period of the first generic applicant expires.

112. Upon receiving final approval of its ANDA for alendronate sodium from the FDA, Apotex intends to and is prepared to enter the U.S. market for generic alendronate sodium.

113. Merck's anti-competitive acts, including those set forth above, have a dangerous probability of harming competition and causing injury to Apotex by preventing the FDA from giving Apotex final approval to market its alendronate sodium drug product as a therapeutic equivalent to Merck's Fosamax® until the

expiration of the 30 month stay or until the first generic filer enters the market, whichever is later.

114. But for Merck's anti-competitive acts, including presenting Apotex with the sham covenant not to sue, Apotex would likely be able to obtain a court decision finding the patents asserted by Merck to be invalid and/or not infringed, which decision would terminate the 30 month stay and trigger the 180 day exclusivity period of the first generic filer, thus allowing Apotex and any other secondary generic applicants to enter the market for generic alendronate sodium on February 6, 2008, the same time as the first generic applicant(s) can enter the market.

115. Merck's anti-competitive acts, including those set forth above, will cause injury to Apotex by delaying its entry into the generic market for alendronate sodium for at least the first 180 days, thus allowing the first generic applicant(s), as well as Merck's own generic version, to establish market shares, and allowing the first generic applicant(s) to make excessive profits before prices fall once the secondary generic manufacturers are allowed to enter the market. Apotex and the other secondary generics will thereby be at a competitive disadvantage as compared to the first generic applicant(s).

116. Merck's anti-competitive acts, including those set forth above, will also cause injury to consumers who will pay higher prices for the generic version of alendronate sodium during the first 180 days after the first generic applicant(s) enters the market because Apotex and other secondary generic manufacturers will be prevented from entering the market during that 180 day period.

**COUNT I – DECLARATORY RELIEF**

117. Apotex repeats, realleges and incorporates by reference each of the allegations of paragraphs 1 through 116 as if set forth fully herein.

118. ~~5. The ‘329~~The relevant claims in the ‘329, ‘801, and ‘801+294 patents are invalid for at least the reasons set forth in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005).

119. ~~6.~~ Apotex cannot be held liable for infringement of the ‘941 patent at least because the claims of this patent are limited to a composition comprising excipients consisting essentially of anhydrous lactose, microcrystalline cellulose, croscarmellose sodium, and magnesium stearate; whereas, Apotex’s tablets will not comprise lactose (either anhydrous or hydrous) or croscarmellose sodium, but will comprise as excipients only manitol, microcrystalline cellulose and magnesium stearate.

120. ~~7.~~ Apotex cannot be held liable for infringement of the ‘590, ‘410, and ‘004 patents at least because the claims of those patents are limited to a tablet comprising a diluent selected from anhydrous lactose and hydrous fast flow lactose; whereas, Apotex’s tablets will not comprise anhydrous lactose or hydrous fast flow lactose.

121. ~~8.~~ Apotex cannot be held liable for infringement of the ‘726, ~~‘207,~~726 and ~~‘294~~207 patents at least because the claims of those patents are limited to anhydrous Alendronatealendronate sodium; whereas, Apotex’s tablets will not contain anhydrous Alendronatealendronate sodium.

122. ~~9.~~ As a consequence of the foregoing, there exists a justiciable controversy as to whether the ‘941, ‘590, ‘726, ‘207, ‘410, ‘004, ‘329, ‘801, and ‘294 patents are valid and~~or~~ infringed. Apotex is entitled to a declaration that the ‘941, ‘590, ‘726, ‘207,

‘410, ‘004, ‘329, ‘801, and ‘294 patents are invalid and/or not infringed by the products that are the subject of Apotex’s ANDA for alendronate sodium.

COUNT II - ATTEMPTED MONOPOLIZATION

123. Apotex repeats, realleges and incorporates by reference each of the allegations of paragraphs 1 through 122 as if set forth fully herein.

124. This Counterclaim arises under the Antitrust Laws of the United States, particularly the Sherman Antitrust Act, 15 U.S.C. §2.

125. Merck has engaged in a pattern and practice of anti-competitive conduct with the intent of preventing or delaying Apotex from marketing a competing alendronate sodium product for use in the treatment of osteoporosis and Paget’s disease.

126. Such unlawful conduct includes, *inter alia*, creating barriers to competition; initiating sham litigation against Apotex on the nine patents in suit; presenting Apotex with a covenant not to sue and seeking to dismiss this case in order to avoid an adverse judgment on the merits that would terminate the 30 month stay and create a “court decision” triggering event of the first generic applicant’s 180 day exclusivity period; and thereby unlawfully attempting to keep Apotex out of the market for generic alendronate sodium longer than it would otherwise.

127. Merck has engaged in anticompetitive conduct with the specific intent to monopolize and preserve a monopoly for alendronate sodium in the United States.

128. Merck, with full knowledge that the claims of the nine patents asserted in this action against Apotex were either invalid or not infringed by Apotex's proposed alendronate sodium product, deliberately impeded, and continued to deliberately impede, Apotex's efforts to bring its alendronate sodium product to market, including by bringing a baseless infringement action against Apotex for the nine patents at issue, and then presenting Apotex with a covenant not to sue in order to avoid an adverse decision on the merits. Merck brought its baseless action to attempt to monopolize the alendronate sodium market, and for the purpose of eliminating Apotex from competing in this market.

129. As evidenced by its actions with Watson, there is a dangerous probability of Merck's achieving monopoly power through the above-described scheme.

130. The Federal Circuit has steadfastly ruled that there is no reasonable apprehension of suit when a declaratory judgment plaintiff is presented with a covenant not to sue. Unless the Federal Circuit's "reasonable apprehension" test for an actual case or controversy is overruled by the Supreme Court, Merck will continue to be able to file objectively baseless lawsuits, which activate the 30 month stays, and avoid a court decision on the merits that would terminate the 30 month stays by presenting covenants not to sue.

131. Through such conduct Merck is also able to avoid triggering the first generic applicant's 180 day period of exclusivity and thereby limit competition for as long as possible.

**DEMAND FOR JUDGMENT AND PRAYER FOR RELIEF**

WHEREFORE, Apotex prays for judgment:

- ~~A. Finding the '329 and '801 patents are invalid;~~
- A. ~~B.~~ Finding the '941, '590, '726, '207, '410, '004, '004 '329, '801, and '294 patents are invalid and/or not infringed;
- B. ~~C.~~ Finding that this is an exceptional case under 35 U.S.C. § 285;
- C. Awarding Apotex treble its actual damages incurred by Merck's violation of the antitrust laws;
- D. Awarding Apotex injunctive relief prohibiting Merck from engaging in the unlawful acts alleged in this Counterclaim;
- E. ~~D.~~ Awarding to Apotex its costs, expenses, and reasonable attorney's fees;
- F. ~~E.~~ Awarding such other relief as the Court deems just and appropriate.

**JURY DEMAND**

Apotex demands trial by jury for all issues triable by jury.

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Dated: May 9, November 3, 2006

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